Request for Sub-collection under the Generic ICR:
Formative Research and Tool Development
OMB 0920-0840, Expiration Date 01/31/2019

"Developing Tools to Engage Adolescent Men Who Have Sex with Men (AMSM)"

Section A: Supporting Statement

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EXHIBITS

LIST OF ATTACHMENTS

- **Goal of the study:** The goal of the "Developing Tools to Engage Adolescent Men Who Have Sex with Men (AMSM)" project is to conduct formative research to characterize: 1) effective methods of and venues for recruitment into research and HIV prevention activities; 2) fundamental aspects of sexual identity, gender identity, behavior, and protective factors among AMSM and transgender youth; 3) acceptability of HIV prevention strategies (e.g., PrEP, nPEP, testing, school-based sex education, access to services); and 4) correlates of racial and ethnic disparities.
- **Intended use of the resulting data**: Develop tools for use by education agencies, community providers, researchers, and other relevant partners about ways to engage AMSM and transgender youth in prevention activities.
- **Methods to be used to collect**: Facilitate online and in-person focus groups with adolescent sexual minority males and transgender youth including fundamental aspects of sexual identity, gender identity, behavior, protective factors, and acceptability of HIV prevention strategies.
- **The subpopulation to be studied:** Up to 72 individuals, including 48 adolescent sexual minority males ages 13-18 and 24 transgender youth ages 13-24.
- **How data will be analyzed:** Qualitative analysis of online and in-person focus group transcripts and background surveys.

Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Division of Adolescent and School Health (DASH) is requesting approval for 1 year of formative and qualitative data collection under the Formative Research and Tool Development Generic Clearance (OMB #0920-0840, expires 01/31/2019). The project proposes to conduct "*Developing Tools to Engage Adolescent Men Who Have Sex with Men (AMSM).*" In order to better address the HIV prevention needs of AMSM and transgender youth, we need to learn more about the barriers to prevention that currently exist and the protective factors that can be built upon.

Adolescent MSM

In the United States, young men who have sex with men (AMSM) are at especially high risk for infection with HIV or other sexually-transmitted infections (STI). In 2013, more than 80% of new diagnoses of HIV infection among adult and adolescent men were attributable to male-to-male sexual contact, and more than 63% of those infections occurred in minority populations, specifically Black and Latino MSM.[1]

Young MSM are among the most vulnerable groups to HIV infection: of the 232,003 diagnoses of HIV infection among all adults and adolescents from 2009 – 2013, 22% of diagnosed HIV

[1] Centers for Disease Control and Prevention. National Center for HIV/AIDS, Viral Hepatitis, STD & TB Prevention, Division of HIV/AIDS Prevention. HIV Surveillance – Men Who Have Sex with Men (MSM). 2013: http://www.cdc.gov/hiv/pdf/statistics_surveillance_msm.pdf

infections among MSM were among those aged 13-24 years, and 91% of those infections were attributable to male-to-male sexual contact.[2] Though there has been a 19% decrease in overall new diagnoses in the last decade, there has been an 87% increase in both Black and Latino MSM ages 13 to 24.[3] Striking disparities by racial and ethnic group among adolescent and young adult MSM are evident in linkage to and retention in care along the HIV care continuum. We need to better understand attitudes and beliefs of adolescent MSM (AMSM), especially Black and Latino AMSM, toward HIV risk and prevention interventions, and barriers to their being able to access and adhere to PrEP and other biobehavioral prevention innovations.

Transgender Youth

A disproportionate share of transgender women (27.7%)[4] and transgender men (11.8%)[5] are living with HIV infection compared to the general adult population (<1%).[6] These rates are even higher among transgender women of color.[7] There are a number of possible reasons for disproportionate rates of infection among transgender women: sex with cisgender male partners[8,9, 10, 11]; history of homelessness, incarceration, forced sex, survival sex, and unemployment[12, 13, 14, 15]; high burden of negative mental health outcomes in transgender adolescent patients[16]; syndemic factors including low self-esteem, polysubstance use, victimization related to transgender identity, and intimate partner violence. The conflation of transgender women with MSM in HIV prevention ignores the unique vulnerabilities and gender identities of transwomen.[17] This conflation also highlights the barriers to PrEP uptake, including a lack of trans-inclusive PrEP marketing, prioritization of hormone use, and medical mistrust due

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[2] Ibid.

[3] Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. CDC fact sheet: Trends in U.S., HIV diagnoses, 2005-2014. February 2016. https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/hiv-data-trends-fact-sheet-508.pdf

[4] Herbst JH, Jacobs ED, Finlayson TJ, McKleroy VS, Neumann MS, Crepaz N. (2008, January). Estimating HIV prevalence and risk behaviors of transgender persons in the United States: a systematic review. *AIDS Behavior*.

[5] Ibid.

[6] Centers for Disease Control and Prevention. (2015, March 16). HIV/AIDS: Basic Statistics. *CDC.*

[7] amfAR: The Foundation for AIDS Research (2014). Trans population and HIV: Time to end the neglect. Retrieved from: http://www.amfar.org/issue-brief-trans-populations-and-hiv-time-to-end-the-neglect/. As cited in Marquez S, Cahill S (2015, December 1). *Transgender women and pre-exposure prophylaxis for HIV prevention: What we know and what we still need to know*. Boston: National Center for Innovation in HIV Care, the Fenway Institute.

[8] Operario D, Nemoto T, Iwamoto M, Moore T. (2011, December). Risk for HIV and unprotected sexual behavior in male primary partners of transgender women. *Archive of Sexual Behavior.*

[9] Nemoto T, Bodeker B, Iwamoto M, Sakata M. (2014, April). Practices of receptive and insertive anal sex among transgender women in relation to partner types, sociocultural factors, and background variables. *AIDS Care.*

[10] Operario D, Nemoto T, Iwamoto M, Moore T. (2011, April). Unprotected sexual behavior and HIV risk in the context of primary partnerships for transgender women. *AIDS Behavior.*

[11] Sevelius JM, Keatley J, Salma N, Arnold E. (2016, March 10). 'I am not a man': Trans-specific barriers and facilitators to acceptability among transgender women. *Global Public Health*.

[12] Nadal KL, Davidoff KC, Fujii-Doe W. (2014). Transgender women and the sex work industry: roots in systemic, institutional, and interpersonal discrimination. *Journal of Trauma and Dissociation.*

[13] Operario D, Soma T, Underhill K. (2008). Sex work and HIV status among transgender women: systematic review and meta-analysis. *J Acquir Immune Defic Syndr*, *48*, 97–103.

[14] amfAR: The Foundation for AIDS Research. (2014). Trans population and HIV: Time to end the neglect. Retrieved from: http://www.amfar.org/issue-brief-trans-populations-and-hiv-time-to-end-the-neglect/

[15] Garofalo R, D. J., Osmer E, Doll M, harper GW. (2006). Overlooked, misunderstood and at-risk: Exploring the lives and HIV risk of ethnic minority male-to-female transgender youth. *Journal of Adolescent Health, 38*, 230-236.

[16] Reisner SL, V. R., Leclerc M, Zaslow S, Wolfrum S, Shumer D, Mimiaga MJ. (2015). Mental health of Transgender youth in care at an adolescent urban community health center: A matched retrospective cohort study. *Journal of Adolescent Health, 56*(3), 274-279.

[17] Sevelius J, Keatley J., Calma N, Arnold E. (2016). 'I am not a man': Trans-specific barriers and facilitators to PrEP acceptability among transgender women. *Global Public Health*.

to transphobia. There is also a lack of evidence-based interventions to address HIV prevention with transgender youth.[18] Culturally competent interventions must be developed with the needs of transgender youth in mind.

Though the increased risk for HIV infection among AMSM and transgender populations is well documented, particularly for Black and Latino youth, there is still a significant gap in research that can inform the development of culturally specific, evidence-based tools to engage AMSM and transgender youth in HIV-prevention behaviors. Review of existing research and interventions for AMSM (ages vary by study, but range from 15-30 years) concludes that little information is available about the acceptability of and preferences for various HIV prevention interventions. In particular, little is known about AMSM attitudes and behaviors that could aid access to, acceptability of, and adherence to promising biomedical HIV prevention interventions (i.e., pre-exposure prophylaxis medications or PrEP, non-occupational post-exposure prophylaxis or nPEP, microbicides, and earlier detection of infection)[19]. Further, there are outstanding questions about frequency and timing of HIV testing, barriers to retention in care for HIV-positive AMSM, and testing for other STDs, that, if answered, could improve HIV prevention efforts. Even less is known about the acceptability of these interventions among transgender youth.

Within the relative dearth of information on AMSM and transgender youth, even less is known about those 18 years of age and younger. For various reasons including less connection to an LGBT community, evolving sexual identity, greater internalization of sexual and gender minority stigma, lack of disclosure to others, misclassification of gender, need for parental consent, and lack of transportation[20], reaching adolescent MSM (AMSM) and transgender youth is often difficult by traditional methods. Adolescent sexual development further compounds challenges in recruiting and engaging these populations, because common definitions in the literature (e.g., in terms of identity or same-sex behavior) may not yet apply to them. Therefore, most research focuses on those older than 18 years and many studies that recruit in bars or social venues include only young adults over the age of 18 (or 21). This creates some problems when drawing conclusions about AMSM and transgender youth who are underrepresented in current research while also existing at the intersection of both sexual/gender minority status and a unique life course stage.

All of these coinciding changes have implications for clinical practice and HIV prevention programs. It is therefore not likely that HIV prevention efforts aimed at adult populations will adequately address the unique needs of adolescents. Experts argue that AMSM 18 years old and younger deserve a distinct approach and that to accurately understand risk and resiliency in this group requires inclusion of participants under the age of 18.[21] Likewise, the experience of being a gay/bisexual/queer young man or being transgender can isolate these youth from traditional efforts geared at a general adolescent population. The experience of being adolescent, a sexual and/or gender minority, and a racial/ethnic minority calls for a distinctive set of programmatic

[18] Garofalo R, J. A., Kuhns LM, Cotten C, Joseph H, Margolis A. (2012). Life Skills: Evaluation of a theory-driven behavioral HIV prevention intervention for young transgender women. *Journal of Urban Health, 89*(3), 419-431.

[19] Bauermeister et al., 2013, Current HIV Research, 11:7, 520; Mustanski et al., 2011, J Sex Research, 48:2-3, 218-253

[20] Kuhns et al, J Urban Health. 2014 Aug 16

[21] Mustanski et al., 2011, J Sex Research, 48:2-3, 218-253

strategies. However, the information to inform such strategies and tools to facilitate their development and implementation are largely missing.

For the reasons outlined above, there is a need for new tools and guidance for the variety of public health practitioners trying to work with these populations to prevent HIV. This project will increase understanding of the unique individual, interpersonal, and social characteristics of AMSM and transgender youth to provide needed input to improve HIV prevention efforts; the preferences and behaviors of AMSM and transgender youth, and especially those of color, to inform acceptability of and adherence to promising HIV prevention strategies; and translate these findings into HIV prevention tools and guidance for preventing HIV among AMSM and transgender youth that are nationally scalable.

This request is authorized by Title III – General Powers and Duties of the Public Health Service, Section 301 (241.)a. Research and investigations generally (**Attachment 1**).

2. Purpose and Use of Information Collection

This project consists of formative research among AMSM 13-18 years old and transgender youth 13-24 years old to characterize: 1) effective methods of and venues for recruitment into research and HIV prevention activities (see focus group guide, question set 1-3: sex, question set 4-5: HIV prevention); and 2) fundamental aspects of sexual identity, gender identity, behavior, and protective factors (see focus group guide, question set 1: forming relationships and sex, question set 6: identity and support). The proposed information collection is one component of a multi-year project. Future components, which will apply findings to the development of culturally appropriate HIV prevention tools and strategies, will be addressed in separate information collection requests.

The current information collection will involve 2 in-person focus groups with AMSM ages 14-17, 2 online focus groups with AMSM ages 13-18, and 2 online focus groups with transgender youth ages 13-24, as shown in the table below. There will be 8-12 participants per group, totaling 56-72 participants. Online focus groups will utilize an asynchronous platform called "*InsideHeads*" that will allow us to access harder to reach populations, such as rural youth and transgender youth. The online focus groups will split up into two discussion sections, detailed as follows: adolescent MSM focus groups of 13-18 will be split into two discussion groups of 13-15 and 16-18. There will be two transgender focus groups: one for ages 13-17 and the other for ages 18-24, both will have breakout sessions based on sex assigned at birth. These breakout sessions will utilize the same focus group guides and discuss the same topics. The breakout sessions based on age are intended to create a safe space for youth to share information with peers in similar developmental stages. The in-person focus groups have a more narrow age focus (14-17) so that age differences, which will be more apparent in person, do not pose undue influence on the conversation. The breakout sessions based on sex assigned at birth are important because transgender youth may have unique experiences depending on their sex assigned at birth.

FG No.	Type of Focus Group	Sample/ Location	N	Type of Respondents	Age Range	Race/Ethnicity

1	Online	National (urban)	12	AMSM[1]	13-18 years[2]	All
2	Online	National (rural)	12	AMSM[1]	13-18 years[2]	All
3	In person	Philadelphia PA	12	AMSM[1]	14-17 years	Oversample Black
4	In person	Boston MA	12	AMSM[1]	14-17 years	All
5	Online	National	12	Transgender[3]	13-17 years	All
6	Online	National	12	Transgender[3]	18-24 years	All

[1] Cis-gender male attracted to other males, sexually active or inactive
[2] Breakout sessions for ages 13-15 and 16-18
[3] Male assigned at birth or female assigned at birth (breakout sessions for each)

The focus groups will explore fundamental aspects of sexual identity, gender identity, sexual behavior, protective factors, and acceptability of HIV prevention strategies. The focus group guides (**Attachments 3c & 3d)** are included with this submission. We plan to assess similarity and dissimilarity across modality (online and in-person), as well as across the two subpopulations (AMSM and transgender youth).

Exhibit A2.1 Items of Information to be Collected

Variables to be explored	**Data collection tool and citation**	**Study Related Procedures**	**Target Population**
Eligibility criteria; attraction; identity; brief sexual history; age.	Screener – Online and In-person (Attachments 3a & 3b)	Web-based and written eligibility screeners	AMSM and transgender youth
Sexual and gender identity; relationships/sex; sources of information on sexual health and HIV prevention (parents/guardians, schools, health providers); knowledge and acceptability of HIV prevention strategies; identity and support (sexual, gender, and racial/ethnic identity).	Focus group guides - AMSM and Transgender Youth (Attachments 3c & 3d)	Online and in-person focus group	AMSM and transgender youth

3. Use of Improved Information Technology and Burden Reduction

We will be utilizing a combination of online and in-person focus groups.The utilization of an online focus group platform allows us to use an improved information technology that reduces burden to the respondent. We will be utilizing online focus groups to access harder-to-reach populations and to gain more national representation of AMSM and transgender youth. Youth who would not be able to travel to the focus group destination due to cost, distance, or time will have the option to participate in the online focus group. Furthermore, the *InsideHeads* platform has a large panel from which it can recruit participants. Online focus groups will also minimize

the burden of transcription because the discussion is typed and can be extracted at the conclusion of the focus group.

4. Efforts to Identify Duplication and Use of Similar Information

The focus groups will collect key information that the Agency believes is not captured elsewhere. The Agency believes no other data collection effort has been conducted or has been planned to collect similar information for these populations. CDC conducted a review of similar studies prior to the issuance of the contract, and determined that this study is collecting unique information from these populations. Most research to date has focused on those older than 18 years and many studies that access AMSM and transgender youth in bars or social venues include only young adult, not adolescent, AMSM and transgender individuals. This creates some problems when drawing conclusions about AMSM and transgender youth who are underrepresented in current research while also existing at the intersection of both sexual/gender minority status and a unique life course stage. Therefore, our project requires the collection of this new primary data.

5. Impact on Small Businesses or Other Small Entities

This data collection effort involves collaboration with partner organizations located in Philadelphia and Boston. CDC's information collection contractor, The Fenway Institute (TFI), will handle recruitment, screening, and facilitation so as not to burden the partner organizations, and a donation will be made as a token of appreciation for their collaboration. Partner organizations will not have access to private information. Staff at partner sites will only be involved in recruitment. Study staff from TFI will conduct all aspects of data collection and analysis.

6. Consequences of Collecting the Information Less Frequently

The proposed project involves a one-time data collection. There are no legal obstacles to reducing burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

For sub-collection requests under a generic approval, Federal Register Notices are not required and none were published. The 60-Day federal register notice was published for this collection on Thursday, June 25, 2015, Vol. 80, No. 122, pp. 36540. No comments were received.

9. Explanation of any Payment or Gift to Respondents

The use of tokens of appreciation for participation in this study is appropriate because the project seeks to conduct focus groups with a hard-to-reach and highly selective population and ask participants highly sensitive questions about issues such as sexual behavior (Kulka, 1995). We anticipate that increased response rates will lead to improved willingness of youth to participate and to achieve a more accurate representation of the underlying population of interest.

There is a variation in the amount of time required for in-person and online focus groups. Online focus groups will take slightly longer due to a number of factors including login time, understanding the web-based platform, typing out responses, and the asynchronous format of the group. Therefore, the online discussion will take approximately 3 hours compared with the 2 hour in-person focus groups. By conducting focus groups online and in-person, we will be able to compare across modalities, to assess which approach is more successful for recruiting a difficult-to-reach population.

Focus group participants will receive a gift card valued at $50 for a 2 hour in-person focus group or a gift card valued at up to $30 for an online focus group that will take place over 3 days and take a total of 3 hours. Online groups do not happen in real time. The online groups occur asynchronously and the time stated is solely an estimate. There is much more variability in the amount of time it will take the respondent to complete the online focus group. The in-person focus group will take 2 hours regardless.

The need for and amount of the token of appreciation is based, in part, on the fact that other, similar research projects that ask HIV risk behavior questions in the participating areas offer similar tokens of appreciation. In fact, the venues most conducive to this research often have numerous on-going studies. Thus, we would be competing with local researchers who do offer other forms of tokens of appreciation. Persons at risk for HIV infection have frequently been the focus of health-related data collections, in which tokens of appreciations are the norm (MacKellar et al., 2005; Thiede et al., 2009). Providing tokens of appreciation to our respondents is critical to achieve acceptable response rates.

Tokens of appreciation have been used in other HIV-related CDC data collection efforts such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2014), the Transgender HIV Behavioral Survey (OMB 0920-0794 exp. 12/31/2010), and the Medical Monitoring Project (OMB 0920-0740, exp. 05/31/2015) all of which ask questions similar to those in our study (Shaw et al., 2001). Though these focus groups were conducted in-person, online focus groups should offer similar tokens of appreciation in order to ensure equivalency.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The NCHHSTP Associate Director of Science Office determined that the Privacy Act does apply to the information collection, which is covered under the Privacy Act System Notice 09-20-0136, “Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC”, which enables the Centers for Disease Control and Prevention (CDC) officials to collect information to better

understand disease patterns in the United States, develop programs for prevention and control of health problems, and communicate new knowledge to the health community.

As the nature of this study is to better understand barriers to HIV prevention, we are sensitive to the need to protect personal health information (PHI). To ensure that respondents' PHI is protected, we take several measures to separate personally identifiable information (PII) from study-related data. Contact information collected for the purposes of providing the token of appreciation (i.e., email address and/or telephone number) will be collected and stored securely and separately from responses to screening and focus group questions. We will train researchers who play a role in data collection and analysis in proper procedures for data handling. We will be prepared to describe these procedures in full detail and to answer any related questions raised by respondents.

Access to all data that identify respondents will be limited to research staff with a data collection or analysis role in the project. Such data will be needed only for inviting participants to the focus groups and providing the gift code for tokens of appreciation and will not be used for analyses. All data will be stored on secure, protected servers. Any data sent to CDC will not contain personal identifiers.

In conjunction with the data policy, members of contractor project staff are required to:

- Comply with procedures to prevent improper disclosure, use, or alteration of private information. Staff may be subjected to disciplinary and/or civil or criminal actions for knowingly and willfully allowing the improper disclosure or unauthorized use of information.
- Access information only on a need-to-know basis when necessary in the performance of assigned duties.
- Notify their supervisor, the Project Director, and the organizational Security Officer if information has either been disclosed to an unauthorized individual, used in an improper manner, or altered in an improper manner.
- Report immediately to both the Project Directors and the organizational Security Officer all contacts and inquiries concerning information from unauthorized staff and non-research team personnel.

The security procedures implemented by the project staff cover all aspects of data handling for electronic data. Data files will be stored on encrypted, secure servers. Unless otherwise required by CDC, these files will be destroyed when no longer needed for the project.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval
This study has been reviewed and approved by the TFI IRB (Attachments 6a) which granted a waiver of parental permission for youth ages 13-17 (Attachment 4b). Attachment 6b is the Project Determination and Approval Form provided by CDC/NCHHSTP.

Sensitive Questions

The study entails a few questions about gender identity which may be deemed sensitive. These questions are necessary to ask as they directly address the overarching research questions of the study, and will allow CDC DASH to better meet the needs of transgender youth in research and programmatic efforts.
There is a minimal risk that some questions may make respondent feel uncomfortable. The consent includes a statement about this risk and informs participants that they may choose not to answer a particular question if they wish and/or end the study at any time.

This study is an initiative aimed to assess barriers and facilitators of HIV prevention. As such, our study entails discussion of sensitive HIV-related information. We plan to ask the following questions that may be sensitive to participants:

1. **AMSM and Transgender Youth Screener**

Potentially Sensitive Questions	**Justification**
What sex were you assigned at birth (what the doctor put on your birth certificate)? (check one) ○ Male ○ Female	Establishes gender identity of respondent which is a determinant of eligibility
Which of the following describes your gender identity, how you think about yourself? (check all that apply) ○ Male ○ Female ○ Transgender ○ Genderqueer/Gender non-conforming (do not identify as male, female, or transgender) ○ I am not sure of my gender identity ○ I do not know what this question is asking	Establishes gender identity of respondent which is a determinant of eligibility
Which of the following best describes you? ○ Heterosexual (straight) ○ Gay or lesbian ○ Bisexual ○ Queer ○ Questioning (not sure of my sexual orientation)	Identifies sexual orientation or affiliation with sexual minority categories and is a determinant of eligibility.
During your life, who have you had oral, vaginal/frontal, or anal sex with? (check one) ○ Males only ○ Females only ○ Both males and females ○ I have not had oral, vagina/frontal, or anal sex	Establishes sexual activity profile of respondent
Who are you sexually attracted to? (check one) ○ Males only ○ Females only ○ Both males and females ○ I don't have sexual attractions	Sexual attraction is a way to identify eligible respondents who may not identify as a sexual minority and have not had sex with a man
How old are you? (write-in)	Age is a determinant of eligibility
ONLINE SCREENER: Please indicate your race or ethnic background. Are you….? SELECT ONE	Responses will be assessed to see if

Ethnicity ○ Hispanic or Latino ○ Not Hispanic or Latino SELECT ONE OR MORE *Race:* ○ White ○ Black or African American ○ American Indian or Alaska Native ○ Native Hawaiian or Other Pacific Islander ○ Asian IN-PERSON SCREENER: What is your ethnicity? ○ Hispanic or Latino ○ Not Hispanic or Latino What is your race? I am going to read a list. You can select one or more options from the list. Do you consider yourself… RECORD ALL ANSWERS GIVEN BY RESPONDENT, BUT DO NOT PROBE FURTHER. OPTION #6, "OTHER," MAY BE USED AS A RECORDING OPTION FOR NON-CONFORMING RESPONSES. OPTION #6 SHOULD NOT BE PRESENTED AS A RESPONSE OPTION. {ONE OR MORE CATEGORIES MAY BE SELECTED} ○ White ○ Black or African American ○ American Indian or Alaska Native ○ Asian ○ Native Hawaiian or Other Pacific Islander ○ OTHER	they are similar, or if they vary systematically, by demographic characteristics of the respondents or characteristics of their environments. The online screener uses the OMB-approved race/ethnicity question for self-reported data. The in-person screener uses the OMB-approved race/ethnicity question for an interviewer-administered form.
Where do you live? (check one) ○ City (big or mid-sized, if volunteered) ○ City (small, if volunteered) ○ Suburbs/burbs (of a big or mid-sized city, if volunteered) ○ Suburbs/burbs (of a small city, if volunteered) ○ Anywhere else, sometimes referred to as a rural or semi-rural area, e.g., few stoplights, need to drive miles to get basic supplies like groceries and gas	Responses will be assessed to see if they are similar, or if they vary systematically, by demographic characteristics of the respondents or characteristics of their environments

2. AMSM Youth Focus Group Guide

Potentially Sensitive Questions	**Justification**

Tell us about a guy you think is really cute, maybe he is someone you are attracted to and want to get to know. (Use his first name or initials only.) How did you meet? How would you let him know that you are interested?	Provides insight into attitudes of respondents in regard to sexual attraction and dating/relationships
Who do you talk to about your crushes on guys? What do you talk about? Who can you ask for advice about dating guys? How about dating girls? If you are attracted to girls, are the girls you are attracted to transgender, cisgender, or both?	Identifies avenues of potential social support and sense of connectedness
Who do you talk about sex with? What do you talk about?	Provides insight as to where respondents seek out information about sexual health and who they consider to be a trusted source, which may be a potential dissemination source for developed materials
When you use the word sex, what do you mean? What is sex? What counts as sex?	Provides necessary information that will be helpful in establishing the sexual activity profile of the respondents
Ok, let's talk about parents/guardians. ○ If your parent/guardian had a conversation about sex with you, what did they say? What was helpful about it? What could have been better? ○ Imagine an ideal conversation about sex between a parent/guardian and a guy your age who is sexually attracted to other guys. What would the parent/guardian say? ○ Has your parent/guardian had a conversation like this with you? If no, would you like them to?	Provides insight into how respondents would like to receive sexual health information and the role of parents/guardians as a potential venue for HIV risk reduction efforts
Now, let's think about schools. ○ What, if anything, have you learned about sex at school? What was helpful about it? What could have been better? ○ Imagine that you have been given the opportunity to develop a sex ed class for high school students. What information should be covered? Who should teach it? How?	Provides insight into how respondents would like to receive sexual health information and the role of schools as a potential venue for HIV risk reduction efforts
Let's talk about health providers, doctors and nurses. ○ Tell us about a time you had a conversation about sex with your doctor/nurse. What do you talk about? What was helpful about it? What could have been better? ○ Now, imagine an ideal conversation about sex between a doctor or nurse and a guy your age who is sexually attracted to other guys. What should the doctor or nurse say or do?	Provides insight into how respondents would like to receive sexual health information and the role of medical providers as a potential venue for HIV risk reduction efforts
Sometimes we learn about sex from people and places other than parents/guardians, at school, or from	Provides insight into how respondents would like to receive sexual health

doctors/nurses. These other sources include: on-line, TV/movies, porn, friends, sexual partners, and church. ○ Have you learned about sex from any of these sources? If so, which were helpful? Why? What did you like about them? What could have been better?	information and identifies additional sources of information as potential venues for HIV risk reduction efforts
As a young man who is attracted to guys, is there anything about sex that you would like to know? What is it? How would you like to get that information? Who would you like to get that information from?	Provides insight into how respondents would like to receive sexual health information and identifies additional sources of information as potential venues for HIV risk reduction efforts
One final question before we wrap up this topic. People have and don't have sex for a number of reasons. What are the main reasons you have not had sex?	Provides insight into knowledge and attitudes of respondents regarding the role and importance of sex in their lives
Experts recommend not having vaginal (sometimes called frontal sex) or anal sex, but finding other ways to be intimate like oral sex or hand to genital contact. ○ What do you think about not having vaginal (sometimes called frontal sex) or anal sex, but finding other ways to be intimate like oral sex or hand to genital contact? ○ How realistic is this for younger guys like you to find other ways to be intimate with other guys (other than anal sex)? ○ Now, we are going to ask a couple of questions about sex with cisgender guys and transgender women, because the risk of passing on HIV during sex is higher. o How realistic is it NOT to have vaginal or anal sex with cisgender guys? o How realistic is it NOT to have vaginal or anal sex with transgender women? ○ What would make it hard to do this? ○ What would make it easier to do this?	Provides insight into attitudes, awareness, and perceived barriers and facilitators in regard to performing lower-risk sexual/intimate activities
Experts recommend using condoms and lube every time for vaginal and anal sex (whether you are giving or receiving anal sex). ○ What do you think about using condoms and lube every time for vaginal/frontal and anal sex? ○ How realistic is this for younger guys like you to use condoms and lube every time for anal sex with other guys (whether you are giving or receiving anal sex)? ○ What would make it hard to do this? ○ What would make it easier to do this?	Provides insight into attitudes, awareness, and perceived barriers and facilitators in regard to using condoms and lube
Experts recommend taking a medication called PrEP. Taking a PrEP pill every day can keep a person from getting HIV if they are exposed to it. [PrEP stands for pre-exposure prophylaxis which means taking HIV	Provides insight into attitudes, awareness, and perceived barriers and facilitators in regard to using PrEP

medication to prevent getting HIV before you are exposed to it.] ○ What do you think about this recommendation? ○ How realistic is it to get PrEP from a doctor and take it every day? ○ What would make it hard to do this? ○ What would make it easier to do this?	
Experts recommend getting tested for HIV and then, if you have HIV, taking HIV medications every day. This is a way to help reduce your risk of passing on HIV if you have it. ○ What do you think about getting tested for HIV? ○ How realistic is it to get tested for HIV? ○ What would make it hard to do this? ○ What would make it easier to do this?	Provides insight into attitudes, awareness, and perceived barriers and facilitators in regard to getting tested for HIV
How realistic is it to take medication every day if you have HIV? ○ What would make it hard to do this? ○ What would make it easier to do this?	Provides insight into attitudes, awareness, and perceived barriers and facilitators in regard to taking HIV medication
Experts also recommend getting tested for sexually transmitted infections such as syphilis, gonorrhea and chlamydia and taking medication for a few days to clear them up. This is a way to help reduce your risk of getting and passing on HIV. ○ What do you think about this recommendation? ○ How realistic is it to get tested for sexually transmitted infections and to take medication if you have one? ○ What would make it hard to do this? ○ What would make it easier to do this?	Provides insight into attitudes, awareness, and perceived barriers and facilitators in regard to getting tested for STIs
What words do you use to describe your gender identity?	Establishes gender identity of respondents which is a determinant of eligibility
What words do you use to describe your sexuality? Why?	Establishes sexual orientation of respondents which is a determinant of eligibility
What support do you get related to your sexuality? What is most helpful? What support would you like?	Identifies potential avenues for social support and sense of connectedness
What support do you get related to your race-ethnicity? What is most helpful? What support would you like?	Identifies potential avenues for social support and sense of connectedness
Anything else that you would like to say related to getting support for all parts of who you are?	Identifies potential avenues for social support and sense of connectedness

3. Transgender Youth Focus Group Guide

**Highlighted items are unique to the transgender youth focus group guide, all other items are identical to the AMSM focus group guide.*

Potentially Sensitive Questions	Justification
Tell us about a guy you think is really cute, maybe he is someone you are attracted to and want to get to know. (Use his first name or initials only.) How did you meet? How would you let him know that you are interested? ○ Is the guy you think is cute transgender or cisgender? What does the term cisgender mean?	Provides insight into attitudes of respondents in regard to sexual attraction and dating/relationships
Who do you talk to about your crushes on guys? What do you talk about? What comes up during these conversations? Does being transgender come up? If so, how? Who can you ask for advice about dating guys? How about dating girls? If you are attracted to girls, are the girls you are attracted to transgender, cisgender, or both?	Identifies avenues of potential social support and sense of connectedness
Does the relationship advice that you get support your gender identity (meaning, support you as a transgender youth and respect your gender identity)?	Evaluates the extent to which respondents receive support that is affirming and sensitive to issues affecting transgender and gender nonconforming people
Who do you talk about sex with? What do you talk about?	Provides insight as to where respondents seek out information about sexual health and who they consider to be a trusted source, which may be a potential dissemination source for developed materials
When you use the word sex, what do you mean? What is sex? What counts as sex?	Provides necessary information that will be helpful in establishing the sexual activity profile of the respondents
Ok, let's talk about parents/guardians. ○ If your parent/guardian had a conversation about sex with you, what did they say? What was helpful about it? What could have been better? ○ Imagine an ideal conversation about sex between a parent/guardian and a guy your age who is sexually attracted to other guys. What would the parent/guardian say? ○ Has your parent/guardian had a conversation like this with you? If no, would you like them to?	Provides insight into how respondents would like to receive sexual health information and the role of parents/guardians as a potential venue for HIV risk reduction efforts
Now, let's think about schools. ○ What, if anything, have you learned about sex at school? What was helpful about it? What could have been better? ○ Imagine that you have been given the opportunity to develop a sex ed class for high school students. What information should be covered? Who should teach it? How?	Provides insight into how respondents would like to receive sexual health information and the role of schools as a potential venue for HIV risk reduction efforts

Let's talk about health providers, doctors and nurses. ○ Tell us about a time that the health care you got supported your gender identity. (By supported, I mean made you feel comfortable and cared for by someone knowledgeable about transgender health.) ○ Tell us about a time that the health care you got did not support your gender identity.	Evaluates the extent to which respondents feel that medical providers are affirming and sensitive to issues affecting transgender and gender nonconforming people
Let's talk about health providers, doctors and nurses. ○ Tell us about a time you had a conversation about sex with your doctor/nurse. What do you talk about? What was helpful about it? What could have been better? ○ Now, imagine an ideal conversation about sex between a doctor or nurse and a guy your age who is sexually attracted to other guys. What should the doctor or nurse say or do?	Provides insight into how respondents would like to receive sexual health information and the role of medical providers as a potential venue for HIV risk reduction efforts
Sometimes we learn about sex from people and places other than parents/guardians, at school, or from doctors/nurses. These other sources include: on-line, TV/movies, porn, friends, sexual partners, and church. ○ Have you learned about sex from any of these sources? If so, which were helpful? Why? What did you like about them? What could have been better?	Provides insight into how respondents would like to receive sexual health information and identifies additional sources of information as potential venues for HIV risk reduction efforts
As a young man who is attracted to guys, is there anything about sex that you would like to know? What is it? How would you like to get that information? Who would you like to get that information from?	Provides insight into how respondents would like to receive sexual health information and identifies additional sources of information as potential venues for HIV risk reduction efforts
One final question before we wrap up this topic. People have and don't have sex for a number of reasons. What are the main reasons you have not had sex?	Provides insight into knowledge and attitudes of respondents regarding the role and importance of sex in their lives
Experts recommend not having vaginal (sometimes called frontal sex) or anal sex, but finding other ways to be intimate like oral sex or hand to genital contact. ○ What do you think about not having vaginal (sometimes called frontal sex) or anal sex, but finding other ways to be intimate like oral sex or hand to genital contact? ○ How realistic is this for younger guys like you to find other ways to be intimate with other guys (other than anal sex)? ○ Now, we are going to ask a couple of questions about sex with cisgender guys and transgender women, because the risk of passing on HIV during sex is higher. o How realistic is it NOT to have vaginal or anal sex with cisgender guys? o How realistic is it NOT to have vaginal or	Provides insight into attitudes, awareness, and perceived barriers and facilitators in regard to performing lower-risk sexual/intimate activities

anal sex with transgender women? ○ What would make it hard to do this? ○ What would make it easier to do this?	
Experts recommend using condoms and lube every time for vaginal and anal sex (whether you are giving or receiving anal sex). ○ What do you think about using condoms and lube every time for vaginal/frontal and anal sex? ○ How realistic is this for younger guys like you to use condoms and lube every time for anal sex with other guys (whether you are giving or receiving anal sex)? ○ What would make it hard to do this? ○ What would make it easier to do this?	Provides insight into attitudes, awareness, and perceived barriers and facilitators in regard to using condoms and lube
Does being transgender affect your ability to ask for what you want from a sexual partner? How and why?	Provides insight into perceived barriers and facilitators linked to gender identity in regard to communication with sexual partners
Experts recommend taking a medication called PrEP. Taking a PrEP pill every day can keep a person from getting HIV if they are exposed to it. [PrEP stands for pre-exposure prophylaxis which means taking HIV medication to prevent getting HIV before you are exposed to it.] ○ What do you think about this recommendation? ○ How realistic is it to get PrEP from a doctor and take it every day? ○ What would make it hard to do this? ○ What would make it easier to do this?	Provides insight into attitudes, awareness, and perceived barriers and facilitators in regard to using PrEP
Experts recommend getting tested for HIV and then, if you have HIV, taking HIV medications every day. This is a way to help reduce your risk of passing on HIV if you have it. ○ What do you think about getting tested for HIV? ○ How realistic is it to get tested for HIV? ○ What would make it hard to do this? ○ What would make it easier to do this?	Provides insight into attitudes, awareness, and perceived barriers and facilitators in regard to getting tested for HIV
How realistic is it to take medication every day if you have HIV? ○ What would make it hard to do this? ○ What would make it easier to do this?	Provides insight into attitudes, awareness, and perceived barriers and facilitators in regard to taking HIV medication
Experts also recommend getting tested for sexually transmitted infections such as syphilis, gonorrhea and chlamydia and taking medication for a few days to clear them up. This is a way to help reduce your risk of getting and passing on HIV. ○ What do you think about this recommendation? ○ How realistic is it to get tested for sexually transmitted infections and to take medication if you	Provides insight into attitudes, awareness, and perceived barriers and facilitators in regard to getting tested for STIs

have one? ○ What would make it hard to do this? ○ What would make it easier to do this?	
What words do you use to describe your gender identity?	Establishes gender identity of respondents which is a determinant of eligibility
What words do you use to describe your sexuality? Why?	Establishes sexual orientation of respondents which is a determinant of eligibility
What support do you get related to your sexuality? What is most helpful? What support would you like?	Identifies potential avenues for social support and sense of connectedness
What support do you get related to your race-ethnicity? What is most helpful? What support would you like?	Identifies potential avenues for social support and sense of connectedness
Anything else that you would like to say related to getting support for all parts of who you are?	Identifies potential avenues for social support and sense of connectedness

Understanding the slight possibility of emotional response or anxiety on the part of the respondent, all respondents will be directed to the appropriate resources and participants are told they can always refuse to answer any questions, or share any information, or interrupt or stop the conversation at any moment. Participants in focus groups experiencing significant distress or requesting services will be assisted immediately by the project staff and referred to the appropriate supportive services, as needed.

If an online participant experiences distress during participation in the focus group, a nurse practitioner/researcher and a member of the study team, will be present during the group and will be available to directly communicate with the participant. The *InsideHeads* platform allows for a backroom chat between a nurse practitioner and the participant, so that the nurse can assess the needs of the participant. The nurse practitioner will also be available over the phone if necessary. Additionally, participants will be provided with contact information for the Trevor Lifeline, run by the Trevor Project (1-866-488-7386). Participants can call this toll-free, confidential line that is available 24/7 if they are experiencing distress. Participants will be provided with this information during the consent/assent process (**Attachments 4a & 4b**). Additionally, the participant will be informed of our procedure for reporting abuse if they disclose that information during the focus group (**Attachment 4f**). The procedure for reporting suspected abuse is for referral to follow-up care, is not part of the formative study, and is therefore not included in the burden table.

12. Estimates of Total Burden Hours and Costs

12A. Estimated Total Burden Hours

We anticipate the screening process to take 5 minutes per respondent for a total of 7 burden hours (**Attachments 3a & 3b**). The online focus groups for AMSM and transgender youth are expected to take 3 hours over the course of 3 days, for a total of 144 burden hours (48

participants online). The in-person focus groups for AMSM and transgender youth are expected to take 2 hours, for a total of 72 burden hours (36 participants in-person). The total estimated burden for focus group participation is 216 hours. The total estimated burden for the project, which includes eligibility screening and focus group participation, is 223 hours.

Exhibit A12.1: Estimated Total Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
AMSM ages 13-18 and Transgender Youth age 13-24	Screener (Attachments 3a & 3b)	72	1	5/60	6
AMSM ages 13-18 and Transgender Youth age 13-24	Online focus group (Attachments 3c & 3d)	48	1	3	144
AMSM ages 13-18 and Transgender Youth age 13-24	In-person focus group (Attachments 3c & 3d)	24	1	2	48
Total					**198**

12B. Estimated Total Burden Costs

The total costs to the respondents are described in Exhibit A12.2. The total estimated cost of the burden to respondents is approximately $1435.50. This cost represents the total burden hours to respondents multiplied by the minimum hourly wage rate ($7.25).

Exhibit A12.2. Estimated Total Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
AMSM ages 13-18 and Transgender Youth age 13-24	Screener (Attachments 3a & 3b)	6	$7.25	$43.50
AMSM ages 13-18 and Transgender Youth age 13-24	Online focus group (Attachments 3c & 3d)	144	$7.25	$1044.00
AMSM ages 13-18 and Transgender Youth age 13-24	In-person focus group (Attachments 3c & 3d)	48	$7.25	$348.00
				Total $1435.50

13. Estimates of Other Total Cost Burden to Respondents or Record Keepers

There are no costs to respondents other than their time.

14. Total Cost to the Government

The estimated cost to carry out the data collection activities over the life of the project is $184,095. This estimate includes the cost of recruitment, focus group facilitation, in-person focus group-related travel, the online focus group platform feeds, as well as the total cost of the tokens of appreciation (gift card worth $50 for 24 in person participants, for a total of $1200 and gift card worth up to $30 for 48 online participants, for a total of $3240).

Exhibit A14.1: Total Cost to the Government

Expense Type	**Expense Explanation**	**Annual Costs (dollars)**
Direct Costs to the Federal Government	CDC, COR (O-5, 0.25 FTE)	$20,328
	CDC, Contracting Officer (GS-12, 0.1 FTE)	$7,426
	CDC, Contracting Officer (GS-12, 0.1 FTE)	$7,426
	Subtotal, Direct Costs	**$35,180**
Cooperative Agreement or Contract Costs	Contract Cost for specific task: The Fenway Institute	$184,095
	Subtotal, Cooperative Agreement or Contract Costs	**184,095**
	TOTAL COST TO THE GOVERNMENT	**$219,275**

15. Explanation for Program Changes or Adjustments

This is an addition to generic information collection request (ICR) # 0920-0840.

16. Plans for Tabulation and Publication and Project Time Schedule

Findings from the focus groups will be provided via e-mail and discussed at regularly scheduled weekly meetings. Tabulation will include descriptive characteristics of study respondents as reported in the screener and transcription of the online and in-person focus groups. The project timeline is detailed in exhibit A16.1.

Exhibit A16.1: Project Time Schedule

Activity	**Time Schedule**

Data collection tools, study protocol development	Completed
Data collection	10/1/2017 (or as soon as OMB approval is received)
Data analysis finalized and report submitted	12 months after OMB approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We do not seek approval to eliminate the expiration date.

18. Exemptions to Certifications for Paperwork Reduction Act Submissions

There are no exemptions to the certification.